



October 20, 2000

9511 '00 OCT 24 P2:02

Dockets Management Branch (HFA-305)
FOOD AND DRUG ADMINISTRATION
5630 Fisher Lane, Room 1061
Rockville, Maryland 20852

RE: Public Docket #95D-0349

Dear Sir or Madam:

Please revise the equipment listing in the SUPAC Equipment Addenda as follows:

- SUPAC-IR/MR Manufacturing Equipment Addendum
- Change name from Diosna (Fluid Air) to Pharmx (Fluid Air)
- | <u>Unit Operations</u> | <u>Class</u> | <u>Subclass</u> |
|------------------------|---------------------------|---------------------------------|
| Blending and Mixing | Convection Mixers | Vertical High Intensity Mixers |
| Granulation | Wet High Shear Granulator | Vertical (Top or Bottom Driven) |
| Drying | Gas Stripping | None Identified |
- Product brochure including picture of the equipment is attached.

Please feel free to call should you require additional information.

Sincerely,

Martin P. Bender
President

Enclosures

cc: Quality Implementation Staff (HFD-357), FDA

95D-0349

C20

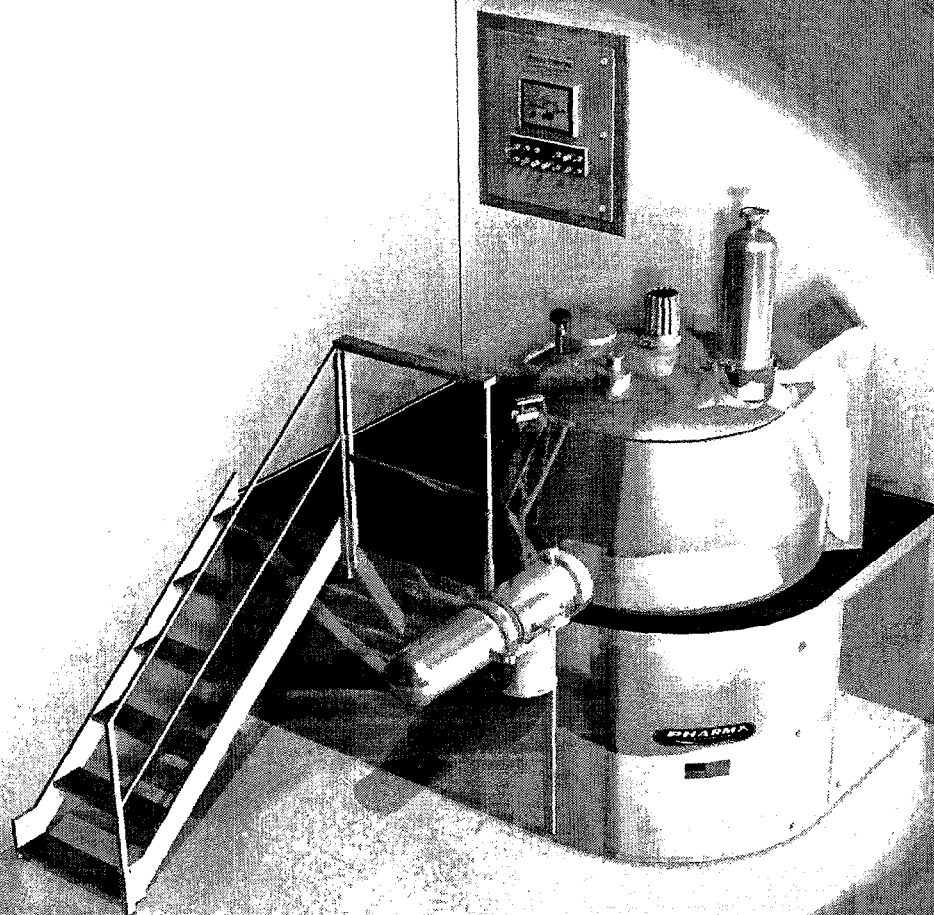
FLUID AIR, INC

2550 White Oak Circle • Aurora, IL 60504-9678 • Phone: 630-851-1200
FAX: 630-851-1244

PHARMX™

HIGH SHEAR GRANULATORS

High intensity mixer for mixing and wet granulating powders.

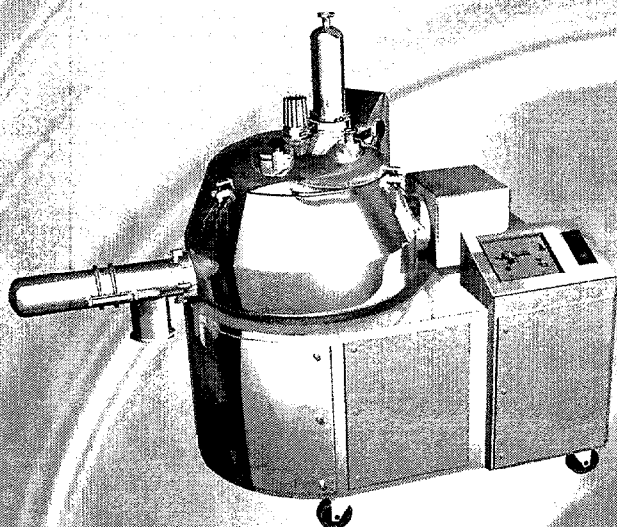


- ▶ Proven Mixer and Chopper Designs
- ▶ 90% Maximum Operating Capacity
- ▶ Mixer Tool Inspection System
- ▶ Power and/or Torque Measuring
- ▶ WIP/CIP Cleaning

**FLUID
AIR**

PHARMX™

HIGH SHEAR GRANULATORS



- ▶ Portable, Stand Alone and Through the Wall Base Configurations
- ▶ Contained IBC and Vacuum Loading Systems
- ▶ Integrated Wet Milling Systems
- ▶ Automated Liquid Delivery Systems
- ▶ Water Jacketing

MODEL NUMBER	PX1	PX10	PX25	PX50	PX100	PX150	PX250	PX400	PX600	PX800	PX1000	PX1250
BOWL VOLUME (LITERS)	1,2,4,6	10	25	50	99	150	250	401	631	807	984	1202
CHARGE VOLUME MAX. (LITERS)	1-5	9	22	45	89	135	230	361	568	726	886	1082
IMPELLER SPEED MIN. (RPM)	5	1	1	1	1	1	1	1	1	1	1	1
IMPELLER SPEED MAX. (RPM)	1077-646	509	374	296	236	205	172	148	127	118	110	103
IMPELLER POWER PACK HP	N/A	1.5	2	5	7.5	10	15	30	60	100	125	125
IMPELLER PEAK HP	1.5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
CHOPPER SPEED MIN. (RPM)	500	500	500	500	500	500	500	500	500	500	500	500
CHOPPER SPEED MAX. (RPM)	6000	4000	4000	4000	3000	3000	3000	3000	3000	3000	3000	3000
CHOPPER HP	1	1.5	2	3	5	7.5	20	30	50	75	100	100

2550 White Oak Circle - Aurora, IL 60504-9678

Phone: 630-851-1200 Fax: 630-851-1244

Email: sales@fluidairinc.com

Web: www.fluidairinc.com

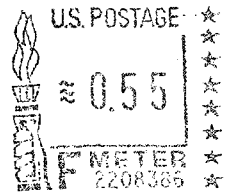
**FLUID
AIR**

24101

ST. CLA

IRST. CLA

FIRST. CLASS



FIRST CLASS MAIL



2550 White Oak Circle
Aurora, Illinois 60504-9678
630-851-1200

TO:

Dockets Management Branch (HFA-305)
FOOD AND DRUG ADMINISTRATION
5630 Fishers Lane, Room 1061
Rockville, MD 20852